REMARKS

Entry of the foregoing and favorable consideration of the subject application, in light of the following remarks, are respectfully requested.

By the foregoing amendment, claims 16-21 have been canceled without prejudice or disclaimer to the subject matter recited therein. Additionally, claims 22-26 have been amended and new claims 31-34 have been added. Support for the amendments to claims 22-26 can be found throughout the originally-filed application. For example, on at least page 1, lines 7-9, page 3, lines 5-10, and page 4, lines 16-25, the specification of the originally-filed application specifically states that an aspect of the present invention relates to an inhibitor of *Helicobacter pylori* colonization that comprises the glycoprotein as an active ingredient, as well as pharmaceutical compositions and foods comprising the inhibitor. Additionally, on at least page 3, line 25 through page 4, line 5, and page 5, lines 13-18, the specification of the originally-filed application states that the glycoprotein active ingredient can be obtained by contacting a glycoprotein-containing substance from whey of bovine milk or albumen of chicken eggs with *Helicobacter pylori* urease, and isolating the glycoprotein specifically bound to the urease. Support for new claims 31-34 can also be found throughout the originally-filed application. For instance, support for new claims 31-32 can be found at least on page 25, line 8 through page 26, line 4, and support for new claims 33-34 can be found on at least page 5, lines 15-18. Hence, no new matter has been added by the present amendment.

In the Advisory Action mailed on July 29, 2003, the Examiner maintained the rejection of claims 16 and 22-26[1] under 35 U.S.C. § 102(b) as allegedly being anticipated by Peterson et al. (U.S. Patent No. 5,505,955). Applicants continue to respectfully traverse this rejection.

As described above, claims 16-21 have been canceled without prejudice or disclaimer to the subject matter recited therein. Thus, the Examiner's rejection and objection to these claims is rendered moot.

It is noted that currently amended claim 22, like claims 19-21, specifies the source of glycoprotein as being from whey of bovine or albumen of chicken eggs. Since claims 19-21 were not previously rejected over the Peterson et al. '995 patent (rather only objected to as being dependent upon a rejected base claim), currently amended claim 22 along with dependent claims 23-26 should also not be rejected for the same reasons.

Moreover, as to currently pending claims 22-26, the Peterson et al. '995 patent fails to disclose, either explicitly or inherently, every element of the claimed invention in the form literally defined in the claim. Thus, the requirement for anticipation has not been met with respect to claims 22-26.

Claim 22, as currently pending, is directed to an inhibitor of *Helicobacter pylori* colonization. The Peterson et al. '995 patent, however, in no way discloses or suggests an inhibitor of *Helicobacter pylori* colonization. Rather, the Peterson et al. '995 patent relates

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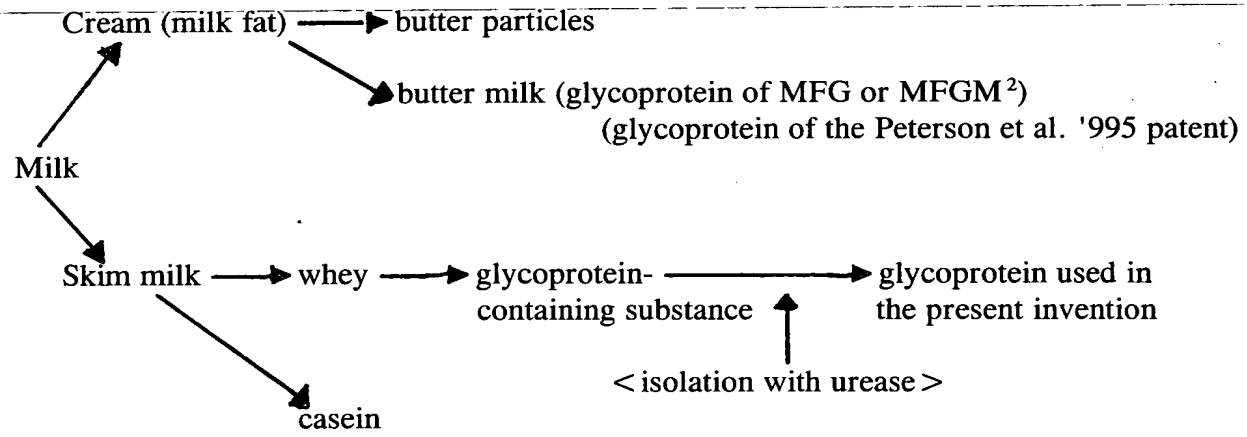
[1] Claims 17-21 were simply objected to as being dependent on a rejected base claim. Claims 27-30 were found to be free of the prior art.

to a prophylactic or therapeutic composition for inhibiting rotavirus infection and an anti-diarrhetic product or kit.

Additionally, the inhibitor of claim 22 consists essentially of a glycoprotein which is prepared by contacting a glycoprotein-containing substance from whey of bovine milk or albumen of chicken eggs with *Helicobacter pylori* urease, and isolating and purifying the glycoprotein specifically bound to the urease. The glycoprotein of the Peterson et al. '995 patent, on the other hand, is derived from human milk fat globules (human MFG). The glycoprotein derived from MFG is mainly contained in butter milk which comes from the cream (milk fat) fraction whereas the glycoprotein derived from whey comes from the skim milk fraction. This difference in source is depicted below.



As shown above, the glycoprotein in the claimed inhibitor is obtained by the additional isolation procedure utilizing the high affinity adsorption to *Helicobacter pylori* urease. Due to this procedure, the glycoprotein of this invention is isolated and purified

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[2] MFGM stands for milk fat globule membrane.

and the resulting glycoprotein has remarkably excellent ability for the inhibition of *Helicobacter pylori* colonization, as apparent from Figure 2 of the present application. (See also the attached Exhibit 1 which is a copy of Figure 2 marked up to clearly show the IC_{50} of the glycoprotein of the present invention.)

As previously presented, Exhibit A which was attached to the Amendment and Reply filed on January 22, 2003 shows that the glycoprotein from MFGM (the glycoprotein of the Peterson et al. '995 patent)[3] has IC_{50} values of 323.8 - 397.3 μg/ml. Namely, the glycoprotein from whey, prior to subjecting to the aforementioned isolation and purification procedure, has an affinity to *Helicobacter pylori* urease 100 times as high as that of glycoprotein from MFGM. Thus, it is apparent that the glycoprotein according to this invention is predominantly and preferentially adsorbed to *Helicobacter pylori* urease in comparison with the glycoprotein of the Peterson et al. '995 patent.

Furthermore, according to Figure 2, the glycoprotein-containing substance from whey of bovine milk such as the high molecular weight whey protein concentrate obviously contains high level of the glycoprotein of the invention. Even if the whey protein concentrate contains a small amount of the glycoprotein of the Peterson et al. '995 patent, the glycoprotein of the Peterson et al. '995 patent should be removed by the isolation procedure utilizing the adsorption of *Helicobacter pylori* urease and thus an amount of the

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[3] MFG comprises MFGM and butter particles. Glycoprotein is contained in membranes. Therefore, the glycoprotein from MFGM is substantially the same as that from MFG.

glycoprotein of the Peterson et al. '995 patent in the claimed inhibitor is nothing or vanishingly low.

As mentioned above, the glycoprotein according to applicants' invention and the glycoprotein of the Peterson et al. '955 patent differ in at least its source, process for preparation, and properties (IC_{50} values, *i.e.* inhibitory activity of H. pylori colonization). Thus, the glycoprotein recited in claim 22, and dependent claims 23-26, is clearly distinguishable from the glycoprotein of the Peterson et al. '995 patent.

The Peterson et al. '995 patent does not disclose, either literally or inherently, every element of applicants' claimed invention and thus fails to satisfy the requirements for anticipation. Accordingly, withdrawal of the rejection under 35 U.S.C. § 102(b) over the Peterson et al. '995 patent is respectfully requested.

In the event that there are any questions relating to this Preliminary Amendment, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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EXHIBIT 1

Fig. 2